DIA

Latin America Annual Meeting

March 6-8 | Virtual Meeting

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Overview

DIA is thrilled to announce our 2023 *Latin America Annual Meeting* (formerly known as *Latin America Regulatory Conference*) that will include opportunities for networking and knowledge sharing with key stakeholders influencing the advancement and implementation of initiatives in Latin America and the Caribbean. This new meeting expands in scope from our previous meetings discussing topics relating to the Latin America region, and presents the following three tracks: Regulatory, Clinical and Pharmacovigilance. Cross-track sessions provide the opportunity to discuss key connection points across major components of regulatory, clinical and pharmacovigilance initiatives, efforts and collaboration within these functional areas in an organization or company. Join us to discuss multi-regional cooperation, global harmonization, lessons learned, and best practices to stimulate discussion and foster collaboration amongst stakeholders in Latin America and the Caribbean.

Registered attendees will receive access to all session recordings for 2 full months post-conference! This allows you to remain flexible with your schedule and not worry if you need to miss a session. Have a conflict with the dates of the conference? Register anyway and you will receive access to the recordings!

**The primary language is English, however simultaneous interpretation in Spanish will be available during this conference.*

Who Should Attend?

Professionals involved in:

- Academia
- Benefit-Risk Assessment and Communication
- Clinical Research and Development
- Clinical Operations
- CROs/Vendors
- Drug Regulation
- Drug Safety/Pharmacovigilance
- Global Submission/Project Management
- Government Affairs
- Manufacturing
- Medical and Scientific Affairs
- Medical Communication
- Medical Information
- Medical Product Safety Assessment
- Pharmacoepidemiology
- Policy and Intelligence
- Post-Market Studies
- Quality Assurance and Compliance
- Real-World Evidence
- Regulatory Agencies
- Regulatory Affairs, Operations, and Strategy
- Research and Development
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Strategic Sourcing/Planning

Schedule At-A-Glance

Track A: Regulatory **Track B:** Clinical **Track C:** Pharmacovigilance

DAY ONE | MONDAY, MARCH 6

Sessions are held in ET

10:00-11:00AM

Welcoming Remarks and Keynote: Regulatory Reliance to Inform Quality National Decisions: Looking at the New Normal

Samvel Azatyan, MD, PhD, Team Lead, Regulatory Convergence and Networks (RCN/REG) World Health Organization (WHO), Switzerland

11:30AM-1:00PM

Session 1: BREAKOUT SESSIONS

Tracks A, B: Regulatory and Clinical Priorities, Plans, Projects and Updates from Regulatory Authorities

Track C: Pharmacovigilance Regulatory Requirements: Challenges and News for the Future

1:30-2:45PM

Session 2: BREAKOUT SESSIONS

Tracks A, B: Good Regulatory Practices & Regulatory System Strengthening

Track C: Strengthening Pharmacovigilance in LATAM and Opportunities for Synergies

3:00-4:15PM

Session 3 Plenary: Ask the Regulators

DAY TWO | TUESDAY, MARCH 7

10:00-11:15AM

Session 4 Plenary: Where Does LATAM Stand with Reliance?

11:45AM-1:00PM

Session 5 Plenary: Building Strong Regulatory Systems for Medical Devices and In Vitro Diagnostics: Foundational Principles, Current Efforts and Opportunities

1:30-2:45PM

Session 6: BREAKOUT SESSIONS

Tracks A, B: The Journey of ICH Implementation in LATAM and Opportunities for Further Harmonization

Tracks C: Patient Centricity as a Key Component for Successful Pharmacovigilance Strategies (Part I)

2:45-3:15PM

Exhibitor Sponsor Case Study, hosted by WCG Clinical: Best Practices for Clinical Research Coordinator's Communication and Training in a Multi-regional Setting

3:15-4:30PM

Session 7: BREAKOUT SESSIONS

Tracks A, B: ICH Q12 Implementation, Progress and Future Opportunities

Track C: Patient Centricity as a Key Component for Successful Pharmacovigilance Strategies (Part II)

DAY THREE | WEDNESDAY, MARCH 8

10:00-11:15AM

Session 8: BREAKOUT SESSIONS

Tracks A, B: Digital Health Innovation and Rising Healthcare Technology Trends in Latin America and the Caribbean

Track C: Exploring Different Pharmacovigilance Methods to Strengthen Post-Market Monitoring

11:45AM-1:00PM	**Session 9: BREAKOUT SESSIONS**
	Track A: How to Keep Pace with the Advancement of Innovation and Emerging Technologies while Safeguarding Patients
	Track B: Innovative Approaches to Clinical Development Programs and Trial Design
	Track C: New Era of Solutions, Practices and Demands for Pharmacovigilance Following the Impact of the COVID-19 Pandemic
1:30-2:45PM	**Session 10: BREAKOUT SESSIONS**
	Tracks A, B: New Trends and Technologies in Medical Devices and In Vitro Diagnostics: How Regulators Embrace Innovation for Future-Proofed Regulatory Frameworks
	Track C: The Future of the Pharmacovigilance Professional
3:15-4:30PM	**Session 11 Plenary:** Roundtables and Closing Remarks

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Recognize the evolution of regulatory systems and its impact on healthcare in Latin America
- Define future perspectives, challenges, and opportunities for the regulation of biopharmaceuticals in Latin America
- Describe current drug safety and pharmacovigilance rules and processes, regulatory trends, and expectations for compliance
- Recognize the importance of good regulatory practices for strengthening and improving the performance of sustainable regulatory systems
- Analyze opportunities for interaction with HAs and possibilities for joint communication strategies centered around the patient
- Share trends and case of studies on effective reliance practices in the region and discuss major remaining obstacles and recommend a path forward
- Follow the implementation of strategies and plans to strengthen the regulatory systems and guarantee access to medical devices, in vitro diagnostics and other related medical products
- Discuss trends on general collaboration and convergence in the region while exploring ICH implementation in Latin America
- Recognize the importance of input from patients for effective decision-making strategies for pharmacovigilance
- Identify the different regulatory strategies on ICH Q12 implementation, based on local regulatory environments and complexities
- Describe the different aspects of digital health technology (DHT) standards and technical guidance in Latin America
- Discuss the value of different sources of pharmacovigilance data for signal detection and effectiveness measures of risk minimization strategies
- Develop multidisciplinary regulatory strategies considering emerging regulatory pathways (e.g., orphan drug and accelerated pathways) that allows for sustainable access in Latin America
- Identify the market dynamics of medical devices, combination products, and wearables in Latin America

New Virtual Platform

- Network with your fellow attendees throughout the Latin America Annual Meeting using our new virtual platform!
- Easily navigate our agenda and explore different tracks and sessions
- Save sessions to your calendar
- Schedule 1:1 or group meetings to make new connections or catch up with colleagues
- Access to the live event, as well as access to on-demand recordings for 2 months post-event